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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,826	05/30/2001	John F. Currie	SAIC0045-US	5090

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EXAMINER

KREMER, MATTHEW J.

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/866,826		Applicant(s) CURRIE ET AL.	
Examiner Matthew J Kremer		Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-114 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claim 99 is objected to because of the following informalities. Claim 99 is a duplicate of claim 98. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-25 and 72-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "other data" in line 7 which is unclear as to what the term "other data" is meant to encompass. Claim 72 recites the limitation "other data" in line 7 which is unclear as to what the term "other data" is meant to encompass. Claim 78 recites the limitation "the at least one seal" in line 2 in which there is insufficient antecedent basis. Claim 79 recites the limitation "the at least one seal" in line 3 in which there is insufficient antecedent basis. Claim 81 recites the limitation "the at least one serpentine capillary channel" in line 3 in which there is insufficient antecedent basis. Claim 87 recites the limitation "other data" in line 7 which is unclear as to what the term "other data" is meant to encompass. Claim 92 recites the limitation "other data" in line 7 which is unclear as to what the term "other data" is meant to encompass. The term "other data" has been interpreted to mean any

information that is related to the patient. Claim 92 also recites the limitation "modified" in line 11 which is unclear as to what the term "modified" is meant to encompass.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-12, 16-17, 20, 23-35, 39-40, 43-44, 59-61, 63-72, 74, 76-77, 80, 82, 86, 92-94, and 105-111 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,233,471 to Berner et al. Berner et al. discloses a method and apparatus for obtaining a sample iontophoretically which includes a collection reservoir and a biosensor which can employ physical, chemical, electrochemical, spectrophotometric, polarimetric, colorimetric, or radiometric measurements. (column 13, lines 25-61 of Berner et al.). Berner et al. teaches the use of electronics such as a microprocessor, memory, and a display for operating the sampling system. (column 6, lines 40-50 of Berner et al.). Berner et al. teaches a procedure for correcting the measurement data by measuring the temperature of the biological system. (column 22, line 64 to column 24, line 3 of Berner et al.). Berner et al. teaches the transmission of output data to a pump or insulin delivery system. (column 34, lines 36-40 of Berner et al.). In regard to

claims 4, 11, 64, and 71, means for enhancing permeability of the skin are employed. (column 4, lines 7-11 of Berner et al.). In regard to claims 12 and 35, several collection reservoirs can be employed. (column 14, lines 26-34 of Berner et al.). In regard to claims 5-10, 29-34, 65-70, 76-77, 105, and 108, Berner et al. discloses that the sampling techniques that can be employed include iontophoresis, sonophoresis, suction, electroporation, thermal poration, passive diffusion, lances subcutaneous implants, and laser devices. (column 6, lines 8-25 of Berner et al.). In regard to claims 16-17 and 39-40, the collection reservoir can be a receptacle containing a material which is ionically conductive (water with ions), a sponge-like material, hydrophilic polymer, or a hydrogel. (column 6, lines 26-39 of Berner et al.). In regard to claims 20, 43, and 94, the biosensor can include a reactive surface. (column 8, lines 17-60 of Berner et al.). In regard to claims 23-24 and 109-110, the device compensates for the biological system's temperature or the temperature fluctuations in the biosensor element caused by environmental conditions. (column 22, line 64 to column 23, line 7 of Berner et al.). In regard to claim 93, Berner et al. teaches that the sampler includes materials that are substantially impermeable to the analyte to be detected such as glucose. (column 9, lines 50-52 of Berner et al.). In regard to claims 106-107, Berner et al. teaches that the analytes that can be analyzed include: any specific substance or component that one is desirous of detecting and/or measuring in a chemical, physical, enzymatic, or optical analysis, amino acids, enzyme substrates or products indicating a disease state or condition, other markers of disease states or conditions, drugs of abuse, therapeutic and/or pharmacologic agents, electrolytes, physiological analytes of

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interest, glucose urate/uric acid, carbonate, calcium, potassium, sodium, chloride, bicarbonate, glucose, urea, lactate/lactic acid, hydroxybutyrate, cholesterol, triglycerides, creatine, creatinine, insulin, hematocrit, hemoglobin, blood gases, lipids, heavy metals, and the like. (column 10, lines 39-57 of Berner et al.).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 13, 15, 36, 38, 62, 83, 85, 95-104, 112, and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claims 1, 59, 82, 94, and 105 in view of U.S. Patent 5,176,881 to Sepaniak et al. Berner et al. does not teach that the detector system comprises an optical detection system comprised of light sources effective to excite fluorophores. Berner et al. teaches that the sensing device can employ physical, chemical, electrochemical, radiometric, spectrophotometric, polarimetric, colorimetric, or like measurement techniques. (column 13, lines 25-41 of Berner et al.). Sepaniak et al. teaches a sensor used in the analysis of determining the presence and concentration of an analyte using fluorescence. (column 1, line 60 to column 2, line 9 of Sepaniak et al.). Such a sensor falls within the group of sensors suggested by Berner et al. Therefore, it would have been obvious to

one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include the biosensor of Sepaniak et al. since Berner et al. teaches other measurement techniques can be used and Sepaniak et al. teaches one such measurement technique. In regard to claims 15, 38, 85, and 113, a laser is used. (column 3, lines 44-62 of Sepaniak et al.).

8. Claims 14, 37, 84, and 114 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. in view of U.S. Patent 5,176,881 to Sepaniak et al. as applied to claims 13, 36, 83, and 112, and further in view of U.S. Patent 6,124,597 to Shehada et al. The combination does not teach the use of an LED as the light source. Shehada et al. teaches that in fluorescence detection, lasers and LEDs are suitable substitutes for each other which implies that they are functionally equivalent. (column 15, line 59 to column 16, line 7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute LEDs for the laser in the combination since they are functionally equivalent and Shehada et al. teaches that they are suitable substitutes.

9. Claims 19, 21-22, 42, 87-89, and 96-104 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claims 1, 16, 26, and 94, and further in view of U.S. Patent 5,458,140 to Eppstein et al. Berner et al. does not teach an adhesive on the sampler for adhering to the skin of a subject. Berner et al. teaches the use of straps to attach the sampler to the body. Eppstein et al.

teaches that a strap and adhesive are suitable substitutes for each other for attaching a sampling device on the skin which implies that they are functionally equivalent. (column 17, lines 19-26 of Eppstein et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute an adhesive for the straps to since they are functionally equivalent and Eppstein et al. teaches that they are suitable substitutes for each other. The combination discloses a method and apparatus for obtaining a sample iontophoretically which includes a collection reservoir and a biosensor. The biosensor can employ physical, chemical, electrochemical, spectrophotometric, polarimetric, colorimetric, or radiometric measurements. (column 13, lines 25-61 of Berner et al.). Berner et al. teaches the use of electronics such as a microprocessor, memory, and a display for operating the sampling system. (column 6, lines 40-50 of Berner et al.). Berner et al. teaches the correction of the measurement data by measuring the temperature of the biological system. (column 22, line 64 to column 24, line 3 of Berner et al.). Berner et al. teaches transmitting output data to a pump or insulin delivery system. (column 34, lines 36-40 of Berner et al.). In regard to claims 21-22, Berner et al. does not teach the use a pump for pumping the fluid which promotes the flow of the analyte to the sampler. Berner et al. teaches that the following sampling techniques can be used: iontophoresis, sonophoresis, suction, electroporation, thermal poration, passive diffusion, lances or cannulas, subcutaneous implants or insertions, and laser devices. Eppstein et al. suggests sampling techniques such as needle puncture, hydraulic jet, laser, and electroporation. (column 5, lines 13-20 of Eppstein et al.). This suggests that hydraulic jet sampling is a suitable substitution

for electroporation, needle punctures, and lasers which implies that they are functionally equivalent. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a hydraulic jet sampling method for electroporation, laser sampling, or needle punctures as suggested by Berner et al. since they are functionally equivalent and Eppstein et al. suggests that they are suitable substitutions for each other. In regard to claims 96-100, Berner et al. does not teach the use of the detector system comprises an optical detection system comprised of light sources effective to excite fluorophores. Berner et al. teaches that the sensing device can employ physical, chemical, electrochemical, spectrophotometric, polarimetric, colorimetric, radiometric, or like measurement techniques. (column 13, lines 25-41 of Berner et al.). Eppstein et al. teaches a sensor of the analysis of the presence and concentration of an analyte which detects fluorescence. (column 17, lines 1-18 of Eppstein et al.). Such a sensor falls within the group of sensors suggested by Berner et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include the biosensor of Eppstein et al. since Berner et al. teaches other measurement techniques can be used and Eppstein et al. teaches one such sensor. The combination teaches the use of lectins for binding to glucose. (column 17, lines 1-18 of Eppstein et al.).

10. Claims 18, 41, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claims 16, 39, and 72, and further in view of U.S. Patent 4,526,176 to Bremer et al. Berner et al. does

not teach the use of a seal for retaining the fluid in the reservoir prior to sampling analytes. Berner et al. teaches that the collection reservoir can be a receptacle containing a material which is ionically conductive (water with ions), a sponge-like material, hydrophilic polymer, or a hydrogel. (column 6, lines 26-39 of Berner et al.). It is well known in the art that a breakable seal is used to prevent escape of fluid such as water or hydrogel prior to use. (column 6, lines 11-15 of Bremer et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include a breakable seal as disclosed by Bremer et al. since seals are used to prevent escape of the fluids prior to use.

11. Claims 45-53 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claim 26, and further in view of U.S. Patent 6,393,318 to Conn et al. Berner et al. does not teach a silicon body. Berner et al. teaches that the sampler includes materials that are substantially impermeable to the analyte to be detected such as glucose. (column 9, lines 50-52 of Berner et al.). Conn et al. teaches that silicon elastomers have this kind of property. (column 23, lines 3-31 of Conn et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use silicon for the sampler since Berner et al. teaches that the material should substantially impermeable to glucose and Conn et al. teaches such a material. In regard to claim 46, means for enhancing permeability of the skin is employed. (column 4, lines 7-11 of Berner et al.). In regard to claims 47-53, Berner et al. discloses that the sampling techniques that can

be employed include iontophoresis, sonophoresis, suction, electroporation, thermal poration, passive diffusion, lances subcutaneous implants, and laser devices. (column 6, lines 8-25 of Berner et al.).

12. Claims 54 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. in view of U.S. Patent 6,393,318 to Conn et al. as applied to claim 46, and further in view of U.S. Patent 5,176,881 to Sepaniak et al. The combination does not teach that the detector system comprises an optical detection system comprised of light sources effective to excite fluorophores. Berner et al. teaches that the sensing device can employ physical, chemical, electrochemical, spectrophotometric, polarimetric, colorimetric, radiometric, or like measurement techniques. (column 13, lines 25-41 of Berner et al.). Sepaniak et al. teaches a sensor used in the analysis to determine the presence and concentration of an analyte using fluorescence. (column 1, line 60 to column 2, line 9 of Sepaniak et al.). Such a sensor falls within the group of sensors suggested by Berner et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include the biosensor of Sepaniak et al. since Berner et al. teaches other measurement techniques can be used and Sepaniak et al. teaches one such sensor. In regard to claims 56, a laser is used. (column 3, lines 44-62 of Sepaniak et al.).

13. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. in view of U.S. Patent 6,393,318 to Conn et al. in view of U.S. Patent 5,176,881 to Sepaniak et al. as applied to claim 54, and further in view of U.S. Patent 6,124,597 to Shehada et al. The combination does not teach the use of an LED as the light source. Shehada et al. teaches that in fluorescence detection, lasers and LEDs are suitable substitutes for each other which implies that they are functionally equivalent. (column 15, line 59 to column 16, line 7). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute LEDs for the laser in the combination since Shehada et al. teaches that they are suitable substitutes for each other.

14. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. in view of U.S. Patent 6,393,318 to Conn et al. as applied to claim 46, and further in view of U.S. Patent 5,458,140 to Eppstein et al. The combination does not teach the use a pump for pumping the fluid which promotes the flow of the analyte to the sampler. Berner et al. teaches that the following sampling techniques can be used: iontophoresis, sonophoresis, suction, electroporation, thermal poration, passive diffusion, lances or cannulas, subcutaneous implants or insertions, and laser devices. Eppstein et al. suggests sampling techniques such as needle puncture, hydraulic jet, laser, and electroporation. (column 5, lines 13-20 of Eppstein et al.). This suggests that hydraulic jet sampling is a suitable substitution for electroporation, needle punctures, and lasers which implies that they are functionally

equivalent. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a hydraulic jet sampling method for electroporation, laser sampling, or needle punctures as suggested by Berner et al. since they are functionally equivalent and Eppstein et al. suggests that they are suitable substitutions for each other.

15. Claims 73 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claim 72. Berner et al. does not explicitly teach the use of serpentine capillary channels. Berner et al. teaches that the collection reservoir can include tubes, vial, capillary collection devices, cannulas, and miniaturized etched, ablated, or molded flow paths. (column 6, lines 26-39 of Berner et al.). With such a selection of possible components, Berner et al. is implying that the type of collection device and the shape of the flow path depends upon many considerations such as manufacturing cost, size of the components, and preferred configuration of the sensor. This provides a clear suggestion that the collection reservoir can be modified and that the determination of the most appropriate collection reservoir by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

16. Claims 78-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. as applied to claims 76, and further in view of U.S. Patent 4,526,176 to Bremer et al., and further in view of U.S. Patent 6,464,687 to

Ishikawa et al. Berner et al. does not teach the use of a seal for retaining the fluid in the reservoir prior to sampling analytes. Berner et al. teaches that the collection reservoir can be a receptacle containing a material which is ionically conductive (water with ions), a sponge-like material, hydrophilic polymer, or a hydrogel. (column 6, lines 26-39 of Berner et al.). It is well known in the art that a breakable seal is used to prevent escape of fluid such as water or hydrogel prior to use. (column 6, lines 11-15 of Bremer et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Berner et al. to include a breakable seal as disclosed by Bremer et al. since seals are used to prevent escape of the fluids prior to use. The combination does not teach a method of breaking the seal. Ishikawa et al. teaches the use of a heater to rupture a seal. (column 7, lines 58-62 of Ishikawa et al.). Such a method would fulfill the requirements of rupturing the seal as required by the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include a heater for rupturing the seal as disclosed by Ishikawa et al. since a method of rupturing the seal is required and Ishikawa et al. teaches one such method.

17. Claims 90-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,233,471 to Berner et al. and further in view of U.S. Patent 5,458,140 to Eppstein et al. as applied to claim 87-89, and further in view of U.S. Patent 5,330,527 to Montecalvo et al. The combination does not teach that the adhesive serves to prevent loss of the physiological compatible fluid or that the adhesive is water impermeable.

The combination teaches the use of adhesive as a form of attachment and the use of a hydrogel as a collection reservoir. Montecalvo et al. teaches that adhesives can be used to attach a hydrogel matrix to a patient that protects the hydrogel from the external environment. (column 3, lines 34-38 of Montecalvo et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include the use of an adhesive that is water impermeable for sealing the sensor to the patient since such an adhesive protects the hydrogel from the external environment.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,730,714 to Guy et al. discloses a sampler, a detector system, a memory, a display, a pump, and a controller.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in cursive script that reads "Matthew Kremer". The signature is fluid and extends to the right with a long horizontal stroke.

Matthew Kremer
Assistant Examiner
Art Unit 3736
December 23, 2002

A handwritten signature in cursive script that reads "Eric F. Winakur". The signature is stylized with a large "E" and a long horizontal stroke.

ERIC F. WINAKUR
PRIMARY EXAMINER